K070913

Pg 1 of 3

510(k) Summary

SAPIMED S.P.A.
Via Santi 25-Z.I. D4 Scalo
Alessandria, ITALY 15100
Phone 39-013-1348109

AUG 10 2007

Contact: Mrs. Paola Oddenino

Summary Prepared: February 28, 2007

Trade Name: Sapimed *Self Light* Disposable Anoscope

Common Name: Disposable Anoscope

Classification Name: Anoscope, Non-Powered
Endoscope, AC Powered and Accessories

Predicate Device Identification:

CFR21:876.1500
Product Code:FER/GCP
Device Class:II
Legally Marketed Device:

Company	*Product*	*510(k) #*
Patrick J. O'Regan	O'Regan Disposable Anoscope	K020702
Welch Allyn, Inc	Model #53110 Disposable Anoscope	K810227
North EOS Industries	EOS Brand Disposable Proctoscope	K954614

Description:
The Sapimed *Self Light* ® Disposable Anoscopes are clear, transparent plastic anoscopes in a range of sizes to suit varying clinical needs. Illumination is provided by either cold-light source GLF 100 or pen-light. The anoscopes are provided in the following configurations:

Models A.4018 and 4019 are clear anscopes for a clear and easy rectal examination.

Models A.4023 and 4024 are anoscopes for examination and use in surgical procedures. The *Self-Light*® Disposable Operating Anoscopes are clear, transparent disposable anoscopes for various proctological procedures. Illumination is provided by either

K070913

Pg 2 of 3

coldlight source GLF 100 or pen-light.

Model A.4081 is an operating anoscopes with a curved shape, transparency and length suitable for open and close hemorrhoiectomy, spincterotomy , coleo/ileo anastamosis, anoplasty, etc.

Model A.4082 Basile's cone shaped operating anoscope has a graduated scale visible on the internal part of the instrument.

ModelA.4083 The Beak is a surgical anoscope with a closed and rounded tip and a full-length open channel 2-2.5cm wide

Intended Use:

The Sapimed *Self Light*® Disposable Anoscopes are intended for physician use to examine the anal sphincter and anus, and, using additional accessories, to perform various diagnostic and therapeutic procedures.

Predicate Product Comparison Chart:

Parameter				
Device Name	**Sapimed Disposable Anoscope**	**O'Regan Disposable Anoscope**	**Welch Allyn Disposable Anoscope**	**North Eos Industries Disposable Proctoscope**
Product Code	FER	FER	FER	GCP
K Number		K020702	K810227	K954614
Common Name	Disposable anoscope	Disposable Anoscope	Disposable anoscope	Disposable proctoscope
Intended Use	intended for physician use to examine the anal sphincter and anus, and, using additional accessories, to perform various diagnostic and therapeutic procedures.	intended for physician use to examine the anal sphincter and anus, and, using additional accessories, to perform various diagnostic and therapeutic procedures.	intended for physician use to examine the anal sphincter and anus, and, using additional accessories, to perform various diagnostic and therapeutic procedures.	intended for physician use to examine the anal sphincter and anus, and, using additional accessories, to perform various diagnostic and therapeutic procedures
Material	Plastic	Plastic	Plastic	Plastic

K070913

Pg 3 of 3

Single use	Yes	Yes	Yes	Yes
Packaged	Clean, non-sterile/ Sterile	Clean, non sterile	Clean, non-sterile	Sterile

Similarities and differences between Self-Light Disposable Anoscope and Predicate Products

The Sapimed disposable anoscopes have a similar intended use, technological characteristics and mode of operation as the predicate products, both disposable and reuseable and presents no new questions concerning safety and efficacy.

Shelf Life

Accelerated aging testing was performed to substantiate an expiration of 5 years.

Biocompatibility Testing:

ISO10993 standards

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

AUG 10 2007

Sapimed S.P.A.
c/o Ms. Yoland Smith
Consultant
Smith Associates
1676 Village Green, Suite A
CROFTON MD 21114

Re: K070913
Trade/Device Name: *Self Light*® Disposable Anoscope
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FER
Dated: June 1, 2007
Received: June 28, 2007

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070913

Device Name: *Self Light*® Disposable Anoscope

Indications for Use:

The Sapimed *Self Ligh*®*t* Disposable Anoscopes are intended for physician use to examine the anal sphincter and anus, and, using additional accessories, to perform various diagnostic and therapeutic procedures.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K07 0913

Page __ of ___